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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,087	09/29/2003	Jianzhu Chen	0492611-0507 (MIT 10396)	2178

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,087	CHEN ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23-90,98 and 99* is/are pending in the application.

4a) Of the above claim(s) *1-20,23-37,43-48 and 50-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-42,49,81-90,98 and 99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 25 April 2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 20 October 2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains claims 1-20, 23-38, 43-48, and 50-80, and the subject matter of all remaining claims drawn to shRNA and vectors expressing siRNA or shRNA, drawn to an invention nonelected with traverse in the response filed 1 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

Applicants have submitted an English language abstract of EP1144623 in attempting to remedy the previous submission of said patent which was not submitted in English. However, no new IDS was submitted for the examiner to indicate whether the abstract had been considered. The reference has been placed in the file and will be considered upon submission of a new IDS that lists the abstract. The new IDS should list only the abstract, as that is this is all that has been submitted, and thus all that can be considered.

Response to Arguments--Claim Rejections - 35 USC § 112

Claims 38-42, 49, 84-90, 98 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to methods of inhibiting any transcript associated with a respiratory disorder, or methods of preventing any respiratory disease marked by overexpression or inappropriate expression of any transcript, or methods of treating or preventing any disease or condition associated with overexpression or inappropriate expression of any target transcript of any respiratory virus, comprising administering an siRNA in combination with a cationic polymer. It is noted that claims 81-83, drawn to inhibition of a target transcript of a respiratory virus in a mammalian subject, is considered to have adequate description, because although the claims are broadly drawn to inhibiting any sequence of any respiratory virus, such inhibition is not claimed as having the function of being linked to treating or preventing any disease. It is the lack of nexus linking such a broad genera of structures (any siRNA targeted to any respiratory virus) with such a specific function (treating or preventing any disease) that necessitates this rejection.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all

its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof. The representative sample requirement may be satisfied by supplying structural or functional information, or a combination of both, such that one of skill in the art would be satisfied that applicants were in possession of the genus as claimed. Further, the size of the representative sample required is an inverse function of the unpredictability of the art.

At the outset it is noted that the rejected claims do not recite any sequence identifier relating to a respiratory disorder or disease. Nor do the claims identified by name any particular respiratory disorder or disease. At their most specific, the claims merely recite methods of inhibiting any transcript associated with a respiratory disorder using and siRNA/cationic complex. It is further claimed that via the use of such complexes in the instant methods, "respiratory disorders" will be treated.

In contrast, the specification exemplifies only the use of siRNA oligos complexed with PEI in methods of inhibiting specific elements of the influenza genome in vivo. While the instant specification is considered to provide adequate description for methods of inhibiting influenza virus using such siRNA/cationic complexes, this is not considered to be representative of the breadth claimed, since at their narrowest, the claims are very broadly drawn to methods of inhibiting any transcript associated with any respiratory disorder. Accordingly these claims

embrace, at their minimum, siRNA directed to any sequence of any respiratory virus, known or yet to be discovered, along with any isoform or allele present within any respiratory viral species, or any variant, polymorphic or otherwise, that is within reasonable similarity to these viral families that retain infectivity, such that disease treatment or prevention is achieved. The instant specification is not considered to have described such breadth of structure linked to such breadth of function.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38-42, 49, 81-90, 98 and 99 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Beigelman et al. (US Pre-Grant Pub Number 2003/0148928 A1).

The claims are drawn to methods of inhibiting a transcript associated with a respiratory disorder, or methods of preventing or treating a respiratory disease associated with overexpression or inappropriate expression of any transcript, or methods of inhibiting expression of a target transcript of a respiratory virus, or methods of treating or preventing any disease or condition associated with overexpression or inappropriate expression of any target transcript of any respiratory virus, comprising administering an siRNA in combination with a cationic polymer, wherein said administration may be intravenous or intranasal, or is inhaled, or is

delivered by aerosol, or wherein said inhibition is in the lung, or not in the lung, or wherein said combination is delivered with a delivery enhancing agent which may be an antibody or fragment or ligand.

Beigelman et al. teaches methods of inhibiting a transcript associated with a respiratory disorder, methods of preventing or treating a respiratory disease associated with overexpression or inappropriate expression of any transcript, methods of inhibiting expression of a target transcript of a respiratory virus, and methods of treating or preventing any disease or condition associated with overexpression or inappropriate expression of any target transcript of any respiratory virus, wherein the virus is influenza or RSV or adenovirus, comprising administering an siRNA in combination with a cationic polymer. Beigelman also teaches said methods whereby said administration may be intravenous, intranasal, or inhaled, or is delivered by aerosol, or wherein said combination is delivered with a delivery enhancing agent which may be an antibody or fragment or ligand. Although Beigelman does not explicitly mention inhibition in the lung, such inhibition would be presumed to be inherent, since the method of Beigelman teaches inhibiting viruses known to target the lung, such as influenze and RSV.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER